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C. 510(k) Summary of Safety and Effectiveness

In response to the Safe Medical Devices Act of 1990, the following is a summary of the safety and effectiveness information upon which the substantial equivalence determination is based.

I. General Information

Submitter's Name: Surgical Laser Technologies, Inc.
Address: 147 Keystone Drive, Montgomeryville, PA 18936
Telephone Number: 215/619-3600; Fax number: 215/619-3209
Contact Person: Davis Woodward
Date Prepared: 3/19/01

II. Names

Company Name of Device: SLT LaserPro® CTH Holmium Laser System
Classification Name: Laser Powered Surgical Instrument (and Accessories HFE Laser Fiber delivery systems)
Common Name: Holmium:YAG laser system

Sponsor Name: Surgical Laser Technologies, Inc.
Sponsor address: 147 Keystone Dr, Montgomeryville, PA 18936

III. Primary Predicate Devices

Trimedyne Omnipulse
Coherent VersaPulse
New Star Model 1000

IV. Product Description

The SLT LaserPro® CTH Holmium Laser System is a compact, mobile, self-contained system that generates invisible laser radiation at approximately 2100 nanometers for treatment and a visible red laser beam at 635 nanometers for aiming. The laser emits a pulsed beam which delivers the energy to the treatment site using a fiberoptic delivery system. The system is comprised of the following functional components: a laser console, control and display panel, fiber port for delivery systems, system microprocessor control electronics, a footswitch; operating software and various fiber delivery systems and accessories.

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V. Intended Use; Indications for Use

The intended use of this device, and its optional accouterments, is the same as the intended use of other holmium:YAG surgical laser systems marketed to provide the same effects on tissue, including soft tissue (including fatty and mucosal tissue) and cartilaginous and bony tissue: viz. for incision, excision, resection, ablation, vaporization, coagulation and hemostasis, with or without an endoscope, in contact or non-contact with tissue, with or without a hand piece, in medical specialties including genitourinary surgery, lithotripsy and percutaneous urinary lithotripsy, gynecologic surgery, orthopedic surgery, percutaneous lumbar discectomy, general surgery, otorhinolaryngological surgery, dermatological and plastic surgery and gastroenterological/gastrointestinal surgery.

The HFE Laser Fiber is to be sold sterile and is intended for multiple use. It is a prescription device.

The SLT LaserPro® CTH Holmium Laser System is indicated for incision, excision, resection, ablation, vaporization, coagulation and hemostasis, with or without an endoscope, in contact and non-contact with tissue, with or without a hand piece, in the following indications:

Genitourinary surgery of soft tissue, including: treatment of bladder, urethral and ureteral tumors; superficial urinary bladder tumors; invasive bladder carcinomas; urethral and penile hemangioma; urethral strictures; lesions of the external genitalia; condylomas; bladder neck obstructions.

Lithotripsy and percutaneous urinary lithotripsy, including: fragmentation of urinary calculi, fragmentation of calculi in the ureter and ureteropelvic junction, fragmentation of kidney

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calculi, fragmentation of urethral calculi and treatment of distal impacted fragments of steinstrasse when guide wires cannot be passed.

Gynecological surgery of soft tissue, including condyloma acuminata.

Orthopedic surgery in soft and cartilaginous tissue in small and large joints (excluding the spine), including: knee meniscectomy, knee synovectomy, chondromalacia and tears, loose body debridement, lateral retinacular release, plica removal, ligament and tendon release, contouring and sculpting of articular surfaces, debridement of inflamed synovial tissue, debridement of degenerative knees.

Lumbar discectomy in soft, cartilaginous and bony tissue, including: vaporization of the L4-5 and L5-S1 lumbar discs of the vertebral spine; open, percutaneous and endoscopic spine procedures.

General surgery of soft tissues, including; skin incision, tissue dissection, excision of external tumors and lesions, complete or partial resection of internal organs, tumors and lesions, and tissue ablations; removal of benign and malignant lesions; mastectomy, hepatectomy, pancreatectomy, splenectomy, thyroidectomy, parathyroidectomy, herniorrhaphy, tonsillectomy, lymphadenectomy, partial nephrectomy, pilonidal cystectomy, resection of lipoma, pelvic adhesiolysis, debridement of decubitus ulcer, hemorrhoids, pilonidal cyst removal and repair, debridement of statis ulcer, biopsy, appendectomy, pylorostenotomy, removal of polyps of the sigmoid colon, lysis of adhesions, cholecystectomy.

Otorhinolaryngological (ENT) surgery in soft, mucosal, cartilaginous and bony tissue, including: endosinus surgery, functional endoscopic sinus surgery, turbinate procedures (e.g. turbinectomy), dacryocystorhinostomy (DCR), ethmoidectomy, polypectomy, maxillary antrotomy, frontal sinusotomy, sphenoidotomy.

Dermatologic and Plastic Surgery of soft, mucosal, fatty and cartilaginous tissue, in therapeutic plastic, therapeutic dermatological and aesthetic surgical procedures, including: scars, tattoo removal, vascular lesions (including port wine stains, hemangioma, telangiectasias [facial, leg] and rosacea), corns, papillomas, basal cell carcinomas, lesions of skin and subcutaneous tissue, plantar warts, periungual and subungual warts, debridement of decubitus ulcer, skin tag vaporization.

Gastroenterologic surgery of soft tissue, including: cholecystectomy, lysis of adhesions, appendectomy, biopsy, pylorostenotomy, benign and malignant lesions, rectal polyps of sigmoid colon, gall bladder calculi, biliary/bile duct calculi, benign and malignant neoplasm, polyps, colitis, ulcers, angiodysplasia, hemorrhoids, varices, esophagitis, esophageal ulcer, Mallory-Weiss tear, gastric ulcer, duodenal ulcer, non-bleeding ulcer, gastric erosions, colorectal cancer, gastritis, bleeding tumors, pancreatitis, vascular malformations, telangiectasias, and telangiectasias of the Osler-Weber-Rendu disease.

VI. Rationale for Substantial Equivalence

The comparison of the intended use and technological features of this device to other legally marketed devices indicates that this device is substantially equivalent to legally marketed predicate devices with regard to safety, effectiveness and intended use.

Compared to some of its predicate devices, the LaserPro CTH Holmium Laser System has a relatively small footprint and a transportable weight. SLT believes that the differences between the HFE Laser Fiber and its predicate devices, taken as a whole, are relatively minor and should not raise any concerns regarding the overall safety or effectiveness of the device.

From a clinical perspective and comparing design specifications, the SLT LaserPro® CTH Holmium Laser System and the predicate devices are substantially equivalent and have the same intended use.

VII. Safety and Effectiveness Information

Description statements were relied on to ascertain the intended uses and technological features of legally

marketed devices, and the substantial equivalence to the SLT LaserPro® CTH Holmium Laser System to such legally marketed devices. Performance data demonstrate that the device can be used in its intended uses safely and effectively.

VIII. Conclusion

The SLT LaserPro® CTH Holmium Laser System has been found to be substantially equivalent to similar currently marketed and predicate surgical lasers and accessories. The SLT LaserPro® CTH Holmium Laser System shares the same indications for use, similar design features and similar functional features as currently marketed and predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 1 4 2001

Surgical Laser Technologies, Inc.
c/o Mr. Robert Mosenkis
President
CITECH
5200 Butler Pike
Plymouth Meeting, Pennsylvania 19462-1298

Re: K011409
Trade/Device Name: SLT LaserPro® CTH Holmium Laser System
Regulation Number: 878.4810
Regulatory Class: II
Product Code: GEX
Dated: May 22, 2001
Received: May 23, 2001

Dear Mr. Mosenkis:

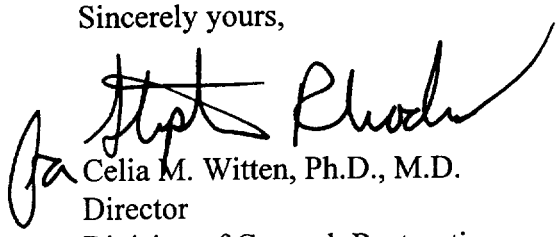
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K011409

Device Name: SLT LaserPro® CTH Holmium Laser System

Indications for Use:

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Genitourinary surgery of soft tissue, including: treatment of bladder, urethral and ureteral tumors; superficial urinary bladder tumors; invasive bladder carcinomas; urethral and penile hemangioma; urethral strictures; lesions of the external genitalia; condylomas; bladder neck obstructions.

Lithotripsy and percutaneous urinary lithotripsy, including: fragmentation of urinary calculi, fragmentation of calculi in the ureter and ureteropelvic junction, fragmentation of kidney calculi, fragmentation of urethral calculi and treatment of distal impacted fragments of steinstrasse when guide wires cannot be passed.

Gynecological surgery of soft tissue, including condyloma acuminata.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K011409

Prescription Use ✓ OR Over-the-Counter Use _____
(Per 21 CFR 801.109)

(Per 21 CFR 801.109)

Indications for Use (cont'd)

Orthopedic surgery in soft and cartilaginous tissue in small and large joints (excluding the spine), including: knee meniscectomy, knee synovectomy, chondromalacia and tears, loose body debridement,lateral retinacular release, plica removal, ligament and tendon release, contouring and sculpting of articular surfaces, debridement of inflamed synovial tissue, debridement of degenerative knees.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K011439

Prescription Use ✓ OR Over-the-Counter Use _____
(Per 21 CFR 801.109)

Otorhinolaryngological (ENT) surgery in soft, mucosal, cartilaginous and bony tissue, including: endosinus surgery, functional endoscopic sinus surgery, turbinate procedures (e.g. turbinoplasty, turbinectomy), dacryocystorhinostomy (DCR), ethmoidectomy, polypectomy, maxillary antrotomy, frontal sinusotomy, sphenoidotomy, hereditary hemorrhagic telangectasia, septoplasty.

Dermatologic and Plastic Surgery of soft, mucosal, fatty and cartilaginous tissue, in therapeutic plastic, therapeutic dermatological and aesthetic surgical procedures, including: scars, tattoo removal, vascular lesions (including port wine stains, hemangioma, telangiectasias [facial, leg] and rosacea), corns, papillomas, basal cell carcinomas, lesions of skin and subcutaneous tissue, plantar warts, periungual and subungual warts, debridement of decubitus ulcer, skin tag vaporization.

Gastroenterologic surgery of soft tissue, including: cholecystectomy, lysis of adhesions, appendectomy, biopsy, pylorostenotomy, benign and malignant lesions, rectal polyps of sigmoid colon, gall bladder calculi, biliary/bile duct calculi, benign and malignant neoplasm, polyps, colitis, ulcers, angiodysplasia, hemorrhoids, varices, esophagitis, esophageal ulcer, Mallory-Weiss tear, gastric ulcer, duodenal ulcer, non-bleeding ulcer, gastric erosions, colorectal cancer, gastritis, bleeding tumors, pancreatitis, vascular malformations, telangiectasias, and telangiectasias of the Osler-Weber-Rendu disease.

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